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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HARRIS, ALANA M	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 05/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/758,575	KAUFMANN ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02/18/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 5-35* is/are pending in the application.

4a) Of the above claim(s) *12-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 5-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendments and Arguments

1. Claims 1 and 5-35 are pending.

Claims 12-35, drawn to non-elected inventions are withdrawn from examination.

Claims 1, 5 and 7 have been amended.

Claims 2-4 have been cancelled.

Claims 1 and 5-11 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejections

Claim Rejections - 35 USC § 102

3. The rejection of claims 1 and 5-11 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication number 2002/0081659 A1 (published June 27, 2002, filing date March 12, 1999) is withdrawn in light of claim amendments. Claims 2-4 have been cancelled.

4. The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Boehringer Mannheim Biochemicals 1991 Catalog, page 557 is withdrawn in light of Applicants' amendment to claim 1.

New Grounds of Rejection and Maintained Rejection

Double Patenting

5. The provisional rejection of claims 1 and 5-11 are under 35 U.S.C. 101 as claiming the same invention as that of claims 1-11 of copending Application No. 10/200,026 (filed July 18, 2002) is maintained. Claims 2-4 have been cancelled.

Applicants aver "[they] will consider filing a terminal disclaimer... when allowable subject matter is indicated in either application.", see Remarks, page 8, fourth paragraph. This point of view has been considered, but found unpersuasive. The rejection will stand until Applicants' applications no longer share the same claimed subject matter.

Claim Rejections - 35 USC § 112

6. The rejection of claims 1 and 5-11 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained. Claims 2-4 have been cancelled.

Applicants argue that the state of the art has progressed considerably and one of skill in the art would be cognizant of advanced methods of protein chemistry since 1988, publication date of Lazar referenced in the first action on the merits (FAOM) mailed November 18, 2004, see Remarks, page 7, paragraph 3. Applicants further their argument stating "[t]he information in ...Lazar...simply constitutes part of the knowledge in the art ...when substituting an amino acid." It is inferred from Applicants' response that the submitted amendments have obviated the instant rejection and should be

consequently withdrawn. The Examiner has considered these arguments and found these points of view unpersuasive.

While Applicants have amended the claims to no longer read on polynucleotide fragments the rejection is maintained. Although Lazar was published in 1988 the state of the art is not far removed from the fact that when changes are made in a nucleic acid sequence the product may not yield products with the same biological activity. The protein of the instant application is denoted as human Out at First (hsOAF). According to the specification it can be used as a marker for the diagnosis of breast tumor metastasis, in the preparation of antibodies and useful in drug development, see page 2, lines 15-17; bridging paragraph of pages 9 and 10; and page 11, lines 2-13.

Applicants' specification has not provided enabling disclosure in which a definitive breast cancer diagnosis or implementation of the claimed polynucleotide in assays can be made with any complement of SEQ ID NO: 2 sharing 90% sequence identity, nor the full-length sequence of SEQ ID NO: 2. The analysis set forth in the FAOM, paragraph 4 is still necessary. And while the Patent Office does not require Applicants to produce astonishing results, the specification must bear some resemblance to what is considered essential to the invention. It is questionable that one of ordinary skill in the art would be able to arbitrarily select nucleic acid residues that yield between one and ten substitutions within SEQ ID NO: 2 and implement this protein in the suggested methods listed in the specification. The specification does not provide sufficient guidance as to what residues should be replaced and what is the barometer or standard used in assessing if these substitutions would significantly affect the folding or

activity of the protein. The specification and the claims are remiss of support enabling the skilled artisan to implement SEQ ID NO: 2 in any form of cancer diagnosis. The specification does not enable one of ordinary skill in the art to definitively assess the incidence of any type of cancer, particularly breast cancer. There is no disclosure designating which complements or what criteria is used for discerning which nucleic acid should be altered to produce a polypeptide with 1-10 conservation amino acid substitutions. Likewise, there is insufficient guidance dictating which residue of SEQ ID NO: 2 could be deleted, changed or mutated to yield a structural and function hsOAF protein. The experimental design presented in the specification lacks information regarding the applicability of SEQ ID NO: 2 and complements thereof in diagnostic methods relative to breast diseases.

Based on the analysis set forth it would require undue experimentation for the skilled artisan to practice this invention because there is no support in the specification for the enablement of the broadly claimed invention. Therefore, in view of the insufficient guidance in the specification, extensive experimentation would be required to enable the claims.

7. Claims 1 and 5-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants broadly claim an isolated nucleic acid molecule that is at least 90% identical to polynucleotides encoding amino acids from:

1 to 273 of SEQ ID NO: 2;

2 to 273 of SEQ ID NO: 2; and

26 to 273 of SEQ ID NO: 2. The said polynucleotide is contained in vector and host cell and produced utilizing art known recombinant technology. The written description in this instant case only sets forth wild type hsOAF (SEQ ID NO: 2 in its entirety) and not molecules with 90% sequence identity to the said sequences. The written description is not commensurate in scope with claims drawn to variants of SEQ ID NO: 2, which have not been defined by functional or structural characteristics.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 115).

With the exception of wild-type hsOAF (SEQ ID NO: 2), the skilled artisan cannot envision the detailed structure or function of the encompassed polypeptides and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Likewise, the skilled artisan

cannot envision the detailed structure or function of nucleic acids that share less than 100% sequence identity to SEQ ID NO: 2. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The polypeptides and molecules germane to the methodology itself are required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, Furthermore, In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement, which defines a genus of nucleic acids by only their functional activity, does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

At the time the application was filed Applicants only had possession of nucleic acids that encode SEQ ID NO: 2 and not nucleic acid sequences that encode polypeptides with reduced sequence homology that may or may not act in the manner suggested by the specification. The specification does not evidence the possession of nucleic acid molecules that may or may not encode hsOAF molecules. Nor does the specification teach any 90% sequence molecules and those molecules which encode a

polypeptide having conservative amino acid substitutions. There is insufficient support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

The full breadth of the claims does not meet the written description provision of 35 U.S.C. 112, first paragraph.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The examiner works a flexible schedule, however she can normally be reached between the hours of 6:30 am to 5:30 pm with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
09 May 2005